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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAGHU, GANAPATHIRAM	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,297	QIN ET AL.	
	Examiner	Art Unit	
	Ganapathirama Raghu	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-64 are pending in this application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 22, 24 and 49, drawn to polynucleotide for Cyclooxygenase-3a (COX-3a) and Cyclooxygenase-3b (COX-3b), vectors, host cell, a kit comprising the polynucleotide and the method of making the polypeptide, consisting of the following SEQ ID NOs: 3, 5, 8 and 10 classified in class 435, subclass 69.1+.

II. Claims 17-21, drawn to isolated polypeptide and fragments, for COX-3a and COX-3b, wherein the polypeptide comprises an amino acid sequence selected from group consisting of the following SEQ ID NOs: 4, 6, 9, and 11 classified in class 435, subclass 189.

III. Claim 23 and 25, drawn to an antibody and a kit comprising the antibody that specifically binds to the isolated polypeptide of at least 70% identity to SEQ ID NO: 4 or 6, classified in class 530, subclass 387.1+.

IV. Claims 26-29, drawn to a kit comprising an agent that is a potent inhibitor of COX-3 activity with unknown structure, substrate for cyclooxygenases and a means to detect cyclooxygenase activity, classified in class 514, subclass 789.

V. Claim 30, drawn to a method of detecting nucleic acid molecule of human COX-3 gene in a test sample under stringent conditions, classified in class 435, subclass 6.

VI. Claim 31, drawn to a method of detecting of human COX-3 protein comprising the steps of contacting the test sample with a specific antibody, classified in class 435, subclass 25.

VII. Claims 32-41, drawn to a method of determining human COX-3 activity comprising the steps of incubating the test sample with agents and test substrates, classified in class 435, subclass 25.

VIII. Claim 42, drawn to a method of identifying variations in human COX-3 gene by isolating the gene and sequencing, classified in class 435, subclass 6.

IX. Claims 43-44, are drawn to a method of reducing human COX-3 expression by antisense oligonucleotides and siRNA, classified in class 435, subclass 6.

X. Claim 45, drawn to a method of evaluating the mechanism of action of an antipyretic/analgesic drug in a cell, classified in class 435, subclass 6.

XI. Claim 46-59, drawn to a method of identifying a compound that alters the prostanoid synthesis catalyzed by human COX-3, classified in class 435, subclass 6.

XII. Claims 60-64, are drawn to a method of identifying ligands and compounds that binds to COX-3, classified in class 435, subclass 25.

The inventions are distinct, each from the other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Inventions I through IV are drawn to products and are patentably distinct from each other. The polynucleotide of group I, the polypeptide of group II, the antibody of group III, and the kits of groups IV, each comprise of nucleic acids, amino acids, and kit components and reagents, that are chemically unrelated, do not require each other for practice; have separate utilities. For example the use of group I polynucleotide in a hybridization reaction versus the group II polypeptide to catalyze a biochemical reaction, are subject to separate manufacture and sale. The groups have acquired a separate status in the art and separate fields of search.

Inventions V through XII are drawn to methods and are patentably distinct. Each of the methods or processes has different steps, using different components and modes of operation with different end results. They do not require each other for practice; have separate utilities. For example, the method of detecting nucleic acid molecule of human COX-3 gene in group VII, the method of detecting COX-3 protein in a test sample in group VIII and the method of detection for the gene variations in group X involve different and distinct steps and modes of operation. Similarly, the method of identifying ligands and compounds that bind to COX-3 in group XV requires different kinds of preparation and mode of use and is subject to separate manufacture and sale.

Inventions I and V, VIII, IX are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of group I can be used in a expression vector for making the polypeptide as opposed to its use in the method of groups V, VIII and IX for

hybridization or detecting gene variations or as an antisense oligonucleotride for reducing the gene expression.

Invention I and methods VI, VII, X, XI, XII are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, polynucleotide of group I are neither used nor made in the methods of groups VI, VII, X, XI and XII. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions II and VI, VII, X, XI, XII are related as products and methods or process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of group II can be used to raise specific antibodies as opposed to its use as enzyme to catalyze a reaction in groups VIII and XI or as a binding polypeptide in group VI or for evaluating analgesic/antipyretic action of drug in a cell in group X or for identifying compounds and ligands that bind to the polypeptide in groups XI and XII.

Invention II and methods V, VIII, IX are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case polypeptide of group II are neither used nor made in the methods of groups V,

VIII and IX. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions III and VI are related as products and methods or process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of group III can be used as a therapeutic as opposed to its use as detecting agent for the polypeptide in group VI.

Invention III and methods VII through XII are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, antibody of group III are neither used nor made in the methods of groups VII through XII. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions IV and VII are related as products and methods or process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the inhibitory agent of group V can be used as a therapeutic agent as opposed to its use to inhibit COX-3 of group VIII *in vitro*.

Invention IV and methods V, VI, VIII through XII are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they

have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, kit of group IV is neither used nor made in the methods of groups V, VI and VIII through XII. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Election of Sequence

Groups I and II contain claims directed to the following patentably distinct species of the claimed invention: the various sequences recited in the claims (Group I polynucleotide sequences with SEQ ID NOs: 3, 5, 8 and 10 and Group II amino acid sequences with SEQ ID NOs: 4, 6, 9, and 11). Furthermore these sequences have different structure and function.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single appropriate disclosed species i.e., a single SEQ ID NO: associated with the respective group for prosecution on the merits to which the claims are restricted. Note that this is a restriction requirement to sequence and NOT a species election.

MPEP 803.04 states: Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141et seq. It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims. Examination will be restricted to only the elected group and the elected amino acid /nucleotide sequence.

Hence, the above inventions have acquired separate status in the art and separate fields of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Rejoinder of restricted inventions

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this

application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652

November 17, 2005